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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,532	12/21/2001	Szu-Min Lin	ASP-54	5937
27777	7590	07/01/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			CHORBAJI, MONZER R	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

H2 ✓

Office Action Summary	Application No. 10/029,532	Applicant(s) LIN, SZU-MIN	
	Examiner MONZER R CHORBAJI	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/23/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 4; applicant uses the phrase "connectable to the inlet port and to the outlet port". The drawings and the specification do not provide elements in the figures nor teachings to understand the meaning of this phrase. In examining claim 1, this limitation is considered that by circulating the sterilant through the inlet and the outlet it means that the source of sterilant is connectable to both ports. The meaning of "connectable" is considered as "joined or related".

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 8-12, and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanderson (U.S.P.N. 4,754,595).

With respect to claims 1 and 9, Sanderson teaches a method and a system for sterilizing items (col.1, lines 9-19) by performing the following: placing items into a sealed sterilization container (col.5, lines 40-44, the sealed container being the bag 18), connecting a source of sterilizing fluid to the container (col.6, lines 10-12 such that the source of the sterilizing fluid being the steam inside the autoclave and is connected or joined or related to the bag 18 through 20 and 22), flowing sterilizing fluid into the container to sterilize the items (col.6, lines 7-8), disconnecting the container from the source of sterilizing fluid (col.6, lines 12-15), and sealing the container in order to maintain sterility of the items therein (col.6, lines 61-65). Sanderson discloses a sterilization system including the following: a sealed sterilization container (18) having an inlet port (28) and an outlet port (28 such that both ports act at some point as inlets and outlets), a source of sterilizing fluid (steam inside the autoclave) is connectable or joined or related to the inlet (28 through 20) and the outlet (28 through 22) ports, and ports (28) includes a passive microorganism impermeable closure (20 and 22).

With respect to claims 2-4 and 10-12, Sanderson teaches a covering of a vapor permeable, microorganism impermeable material (67), a valve (20), and a chemical vapor (col.5, lines 44-46).

With respect to claim 8, Sanderson system includes baffles (15 and 14).

With respect to claims 14-15, the Sanderson reference teaches flowing steam from the source, which is the interior of the autoclave chamber, into first port (20) through the inside of the container (18) and later out from the second port (22) and back to the source (being the inside of the autoclave chamber). As a result, a continuous flow

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of steam is created from the source into the bag and through the bag and out back to the source.

4. Claims 9-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Langford (U.S.P.N. 4,754,595).

With respect to claim 9, Langford a system for sterilizing items (figure 18) by performing the following: placing items into a sealed sterilization container (col.23, lines 31-32, the sealed container being 180), connecting a source of sterilizing fluid to the container (col.23, lines 34-35), flowing sterilizing fluid into the container to sterilize the items (col.23, lines 50-58), disconnecting the container from the source of sterilizing fluid (col.23, lines 59-64), and sealing the container in order to maintain sterility of the items therein (col.23, lines 62-64).

With respect to claims 10-12 and 14, Langford discloses the following: a microorganism impermeable, vapor permeable material (183A), an automatically closing valve (183A), a chemical vapor (col.10, lines 26-28), and the container has a second port such that the sterilizing fluid flows from a first port to the second port through it (183A).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanderson (U.S.P.N. 4,754,595) in view of Koubek (U.S.P.N. 4,512,951).

With respect claims 5, 13, and 16, Sanderson fails to teach the use of both hydrogen peroxide vapor and a fan. However, Koubek teaches the use of hydrogen peroxide vapor (23) and a fan (17). Thus, it would have been obvious to one having ordinary skill in the art to modify the method and the system of Sanderson to substitute steam for hydrogen peroxide since hydrogen peroxide is known to have a sporicidal activity (Koubek, col.2, lines 9-10). Further it would have been obvious to one having ordinary skill in the art to modify the method and the system of Sanderson to include a fan in order to insure uniform distribution of the inflowing hydrogen peroxide vapors (Koubek, col.3, lines 63-67).

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanderson (U.S.P.N. 4,754,595) in view of Langford (U.S.P.N. 5,443,801).

With respect to claim 6, Sanderson fails to create a pressure differential between the inlet and outlet ports to create a flow of the sterilizing fluid through the container. However, Langford does create a pressure differential between the inlet and outlet ports

by using a pump (184). Thus, it would have been obvious to one having ordinary skill in the art to modify the system of Sanderson to include a pump in order to affect the flow of the sterilizing agent in and out of the capsule (Langford, col.23, lines 50-52).

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanderson (U.S.P.N. 4,754,595) in view of Langford (U.S.P.N. 5,443,801) and further in view of Koubek (U.S.P.N. 4,512,951).

With respect to claim 7, both Sanderson and Langford fail to teach the use of a fan. However, Koubek teaches the use of a fan (17). As a result, it would have been obvious to one having ordinary skill in the art to modify the system of Sanderson to include a fan in order to insure uniform distribution of the inflowing hydrogen peroxide vapors (Koubek, col.3, lines 63-67).

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (U.S.P.N. 5,443,801) in view of Koubek (U.S.P.N. 4,512,951).

With respect to claim 13, Langford fails to teach the use of hydrogen peroxide vapor; however, Koubek teaches the use of hydrogen peroxide vapor (23). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Langford to substitute ozone for hydrogen peroxide since hydrogen peroxide is known to have a sporicidal activity (Koubek, col.2, lines 9-10).

Conclusion

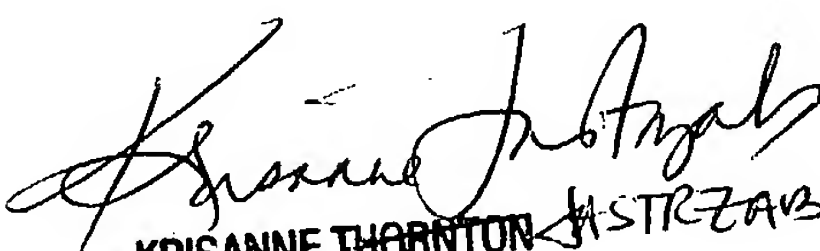
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

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12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji *MRC*
Patent Examiner
AU 1744
06/26/2004


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PRIMARY EXAMINER